

REMARKS

Introductory Comments:

Claims 1-27 were examined in the Office Action under reply and stand rejected under (1) 35 U.S.C §112, second paragraph (claims 1-27); (2) 35 U.S.C. §102 (claims 1-8, 10, 12 and 14-25); and (3) 35 U.S.C. §103(a) (claims 1, 3 and 5-26). These rejections are respectfully traversed as discussed more fully below.

Applicants acknowledge with appreciation the withdrawal of the previous rejections under 35 U.S.C. §102 over Ishi et al., *Hepatology* (1998) 28:1117-1120 and Forns et al., *Vaccine* (1999) 17:1992-2002.

Overview of the Above Amendments:

Claims 2 and 7 have been cancelled and the recitations therefrom have been added to claim 1. Claim 1 has therefore been amended to recite specific boundaries for the E1E2 and E2 antigens and that the immune response is “humoral.” Claim 1 has also been amended to recite that E1E2 antigen “consists of” an E1 polypeptide and an E2 polypeptide and optionally includes an HCV p7 polypeptide. Claim 4 has been amended to track the language of claim 1. Claims 3-6, 8-12, 14, 16, 17, 26 and 27 have also been amended to depend from non-cancelled claims.

Support for the foregoing amendments can be found in the original claims, as well as throughout the application e.g., at page 16, lines 15-29; and page 17, lines 25-29. The foregoing amendments are made without prejudice, without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record. Applicants expressly reserve the right to file one or more continuing applications containing the unamended claims.

Rejection Under 35 U.S.C. §112, Second Paragraph:

Claims 1-27 were rejected under 35 U.S.C. §112, second paragraph as indefinite. The Office contends the claims are “incomplete for omitting essential elements.” In particular, the Examiner argues:

Fournillier et al. teach that NOB responses are only obtained with truncated proteins, not full length (page 7498, column 1, first full paragraph). The recited

structures include “full length” and thus read on wild type which are secreted except for the polynucleotide that lacks p7.

Office Action, pages 3-4. However, applicants disagree with this assessment. Contrary to the Examiner’s statement above, as explained at page 17, lines 1-5 of the application, an E2 polypeptide with deletions at the C-terminus is **secreted** from a cell, while full-length E2 is **retained**. See, e.g., Forns et al., *Vaccine* (1999) 17:1992-2002; Spaete et al., *Virology* (1992) 188:819-830; Ralston et al., *J. Virol.* (1993) 67:6753-6761; and U.S. Patent No. 6,121,020. Additionally, as explained at page 17, lines 22-25, truncated forms that are normally secreted can be anchored in the endoplasmic reticulum using, for example, a KDEL sequence at the C-terminus. Thus, the application describes molecules and conditions responsible for directing intracellular production as opposed to secretion. Thus, the use of functional language in the claim is believed to be proper.

Furthermore, the Office’s assertion that only truncated molecules provide an NOB response is simply inapposite to the data in the present application. As shown in Examples 1 and 2, full-length E2, as well as full-length E1E2 and full-length E1E2 with p7 all demonstrate an anti-E2 NOB antibody titer. The fact that the titers are not as high as those achieved with, for example, the truncated E2-715 molecule is of no avail. An anti-E2 NOB antibody titer within the preferred parameters is still obtained. See, e.g., page 32, lines 13-16 of the specification.

Accordingly, withdrawal of the rejection under 35 U.S.C. §112, second paragraph is respectfully requested.

Rejections Over the Art:

The Office states the previous rejection of claims 1, 3 and 5-26 under 35 U.S.C. §103(a) over Forns et al., *Vaccine* (1999) 17:1992-2002 (“Forns”) has been maintained. However, the sentence in the Office Action that immediately follows this statement explains: “Applicant’s arguments have been fully considered and found persuasive for reasons stated above.” Additionally, the Examiner has not detailed how Forns is being applied and why the applicants’ previous arguments do not serve to overcome the rejection under 35 U.S.C. §103(a) over Forns.

Nevertheless, solely in an effort to advance prosecution, the substance of claim 2 has been added to claim 1. Claim 2 was not rejected over Forns. All remaining claims either

directly or ultimately depend from claim 1. Thus, this basis for rejection has been overcome and withdrawal thereof is respectfully requested.

Claims 1-6, 8, 10, 12 and 15-25 were rejected under 35 U.S.C. §102(a) as anticipated by Fournillier et al., *Hepatology* (1998) 28:1117-1120 (“Fournillier”). Applicants do not agree that Fournillier anticipates the claims. However, in an effort to advance prosecution, applicants have amended claim 1 to incorporate the substance of claim 7, which claim was not subject to this rejection. Thus, this basis for rejection has also been overcome and withdrawal thereof is requested.

Claims 1-5, 7, 10 and 14 were rejected under 35 U.S.C. §102(b) over Yanagi et al., *Proc. Natl. Acad. Sci. USA* (1997) 73:8738-8743 (“Yanagi”). The Office asserts:

The recited fragments in claim 7 do not limit the administered polynucleotide to the recited sequence because claim 1 uses comprising language. Claim 1 recites comprising E1E2 antigen but does not provide any other structural limitations for the wherein clause not secreted so it reads on any polynucleotide that comprises E1E2 antigen.

Office Action, page 5. However, applicants submit the claims indeed distinguish over Yanagi.

In particular, Yanagi pertains to the delivery of a full-length cDNA clone of HCV to chimpanzees. Yanagi does not teach or suggest the delivery of a polynucleotide encoding an HCV E1E2 antigen, wherein the HCV E1E2 antigen “consists of” an HCV E1 polypeptide and an HCV E2 polypeptide and optionally an HCV p7 polypeptide. Accordingly, Yanagi does not teach all of the elements of the claims and therefore fails to anticipate the present claims.

Hybritech Inc. v. Monoclonal Antibodies, Inc., 231 USPQ 81, 90 (Fed. Cir. 1986); *Atlas Powder Co. v. E. I. du Pont De Nemours & Co.*, 224 USPQ 409, 411 (Fed. Cir. 1984). Withdrawal of the rejection over Yanagi is therefore respectfully requested.

CONCLUSION

Applicants respectfully submit that the claims define a patentable invention.

Accordingly, a Notice of Allowance is believed in order and is respectfully requested.

Please direct all further written communications in this application to:

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